

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
TYLER DIVISION

MERCK & CIE, ET AL.

Plaintiffs,

vs.

MACOVEN PHARMACEUTICALS,  
ET AL.

Defendants.

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C.A. NO. 6:12-cv-27-LED

JURY TRIAL DEMANDED

**DEFENDANT MACOVEN'S ANSWER,  
AFFIRMATIVE DEFENSES, AND COUNTERCLAIM**

Defendant, Macoven Pharmaceuticals, L.L.C. ("Macoven"), incorrectly named in the Complaint as Macoven Pharmaceuticals, responds to plaintiffs' Complaint as follows:

1. The allegations of paragraph 1 that this civil action is for infringement of United States Patent Nos. 5,997,915, 6,011,040, 6,254,904, 6,673,381, 7,674,490 and 7,172,778 (collectively the "patents-in-suit"), and purports to arise under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* are admitted. In all other respects, the allegations of paragraph 1 are denied. Further answering, defendant Macoven denies that it has infringed any valid claim of the patents-in-suit.

2. The allegations of paragraph 2 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

3. The allegations of paragraph 3 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

4. The allegations of paragraph 4 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

5. The allegation of paragraph 5 that defendant Macoven has its principal place of business at 33219 Forest West Dr., Magnolia, TX 77354 is admitted. In all other respects, the allegations of paragraph 5 are denied.

6. The allegations of paragraph 6 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

7. The allegations of paragraph 7 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

8. The allegations of paragraph 8 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

9. The allegations of paragraph 9 are admitted.

10. The allegations of paragraph 10 with respect to defendant Macoven are denied and with respect to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. Further answering, defendant Macoven does not contest personal jurisdiction.

11. Defendant Macoven admits that the venue is proper in this judicial district, but avers that venue in this judicial district is inconvenient for the parties and witnesses.

12. The allegation of paragraph 12 that on December 7, 1999, the United States Patent and Trademark Office (“USPTO”) issued United States Patent No. 5,997,915 (“the '915 patent”) is admitted. In all other respects, the allegations of paragraph 12 are denied.

13. The allegations of paragraph 13 are admitted.

14. The allegations of paragraph 14 are admitted.

15. The allegations of paragraph 15 that a true and correct copy of the '915 patent and the re-examination certificate for the '915 patent (issuing on December 13, 2011) are attached as

Exhibit A are admitted. In all other respects, the allegations of paragraph 15 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

16. The allegations of paragraph 16 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

17. The allegations of paragraph 17 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

18. The allegations of paragraph 18 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

19. The allegation of paragraph 19 that on July 3, 2001, the USPTO issued United States Patent No. 6,254,904 (“the '904 patent”) is admitted. In all other respects, the allegations of paragraph 19 are denied.

20. The allegations of paragraph 20 are admitted.

21. The allegations of paragraph 21 are admitted.

22. The allegation of paragraph 22 that a true and correct copy of the '904 patent is attached as Exhibit B is admitted. In all other respects, the allegations of paragraph 22 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

23. The allegations of paragraph 23 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

24. The allegations of paragraph 24 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

25. The allegations of paragraph 25 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

26. The allegation of paragraph 26 that on January 6, 2004, the USPTO issued United States Patent No. 6,673,381 (“the ‘381 patent”) is admitted. In all other respects, the allegations of paragraph 26 are denied.

27. The allegations of paragraph 27 are admitted.

28. The allegations of paragraph 28 are admitted.

29. The allegations of paragraph 29 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

30. The allegations of paragraph 30 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

31. The allegations of paragraph 31 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

32. The allegations of paragraph 32 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

33. The allegation of paragraph 33 that on February 6, 2007, the USPTO issued United States Patent No. 7,172,778 (“the ‘778 patent”) is admitted. In all other respects, the allegations of paragraph 33 are denied.

34. The allegations of paragraph 34 are admitted.

35. The allegations of paragraph 35 are admitted.

36. The allegation of paragraph 36 that a true and correct copy of the ‘778 patent is attached as Exhibit D is admitted. In all other respects, the allegations of paragraph 36 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

37. The allegations of paragraph 37 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

38. The allegations of paragraph 38 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

39. The allegations of paragraph 39 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

40. The allegation of paragraph 40 that on March 9, 2010, the USPTO issued United States Patent No. 7,674,490 (“the ‘490 patent”) is admitted. In all other respects, the allegations of paragraph 40 are denied.

41. The allegations of paragraph 41 are admitted.

42. The allegations of paragraph 42 are admitted.

43. The allegation of paragraph 43 that a true and correct copy of the ‘490 patent is attached as Exhibit E is admitted. In all other respects, the allegations of paragraph 43 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

44. The allegations of paragraph 44 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

45. The allegations of paragraph 45 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

46. The allegations of paragraph 46 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

47. The allegation of paragraph 47 that on January 4, 2000, the USPTO issued United States Patent No. 6,011,040 (“the ‘040 patent”) is admitted. In all other respect, the allegations of paragraph 47 are denied.

48. The allegations of paragraph 48 are admitted.

49. The allegations of paragraph 49 are admitted.

50. The allegation of paragraph 50 that a true and correct copy of the '040 patent is attached as Exhibit F is admitted. In all other respects, the allegations of paragraph 50 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

51. The allegations of paragraph 51 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

52. The allegations of paragraph 52 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

53. The allegations of paragraph 53 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

54. The allegations of paragraph 54 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

55. The allegations of paragraph 55 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

56. The allegations of paragraph 56 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

57. The allegations of paragraph 57 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

58. The allegations of paragraph 58 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

59. The allegations of paragraph 59 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

60. The allegations of paragraph 60 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

61. The allegation of paragraph 61 that defendant Macoven is a pharmaceutical company that develops, markets, and sells pharmaceutical products is admitted. In all other respects, the allegations of paragraph 61 are denied.

62. The allegations of paragraph 62 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

63. The allegations of paragraph 63 that defendant Macoven offers to sell, sells, and distributes certain of its products nationwide, in the State of Texas, and in this judicial district are admitted. In all other respects, the allegations of paragraph 63 as they pertain to defendant Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

64. The allegations of paragraph 64 are denied.

65. The allegations of paragraph 65 are denied.

66. The allegations of paragraph 66 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

67. The allegations of paragraph 67 are denied.

68. The allegations of paragraph 68 are denied.

69. The allegations of paragraph 69 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

70. The allegations of paragraph 70 are denied.

71. The allegations of paragraph 71 are denied.

72. The allegations of paragraph 72 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

73. The allegations of paragraph 73 are denied.

74. The allegations of paragraph 74 are denied.

75. The allegations of paragraph 75 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

76. The allegations of paragraph 76 are denied.

77. The allegations of paragraph 77 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

78. The allegations of paragraph 78 are denied.

79. The allegations of paragraph 79 are denied.

80. The allegations of paragraph 80 are denied.

81. The allegations of paragraph 81 are denied.

82. The allegations of paragraph 82 are denied.

83. The allegations of paragraph 83 are denied for lack all knowledge or information sufficient to form a belief as to the truth of the allegations.

84. The allegations of paragraph 84 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

85. The allegations of paragraph 85 are denied.

86. The allegations of paragraph 86 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

87. The allegations of paragraph 87 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

88. The allegations of paragraph 88 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.



89. The allegations of paragraph 89 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

90. The allegations of paragraph 90 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. Further answering, defendant Macoven denies that any of its accused L-methylfolate products infringe any valid claim of the patents-in-suit.

91. The allegations of paragraph 91 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

92. The allegations of paragraph 92 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

93. The allegations of paragraph 93 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

94. The allegations of paragraph 94 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

95. The allegations of paragraph 95 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

96. The allegations of paragraph 96 are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

97. For its response to the allegations of paragraph 97, defendant Macoven incorporates all of its previous responses to the allegations of paragraphs 1-96.

98. The allegations of paragraph 98 as they pertain to Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

99. The allegations of paragraph 99 are denied.

100. The allegations of paragraph 100 are denied.

101. The allegations of paragraph 101 are denied.

102. The allegations of paragraph 102 that upon information and belief, Defendants have knowledge of the '915 patent by virtue of the identification of the '915 patent on the METANX<sup>®</sup>, Neevo DHA<sup>®</sup> and Cerefolin NAC<sup>®</sup> product labels, package information and marketing materials are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. In all other respects, the allegations of paragraph 102 are denied.

103. For its response to the allegations of paragraph 103, defendant Macoven incorporates all of its previous responses to the allegations of paragraphs 1-102.

104. The allegations of paragraph 104 as they pertain to Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

105. The allegations of paragraph 105 are denied.

106. The allegations of paragraph 106 are denied.

107. The allegations of paragraph 107 are denied.

108. The allegations of paragraph 108 that upon information and belief, Defendants have knowledge of the '904 patent by virtue of the identification of the '904 patent on the METANX<sup>®</sup>, Neevo DHA<sup>®</sup> and Cerefolin NAC<sup>®</sup> product labels, package information and marketing materials are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. In all other respects, the allegations of paragraph 108 are denied.

109. For its response to the allegations of paragraph 109, defendant Macoven incorporates all of its previous responses to the allegations of paragraphs 1-108.

110. The allegations of paragraph 110 as they pertain to Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

111. The allegations of paragraph 111 are denied.

112. The allegations of paragraph 112 are denied.

113. The allegations of paragraph 113 are denied.

114. The allegations of paragraph 114 that upon information and belief, Defendants have knowledge of the '381 patent by virtue of Defendants' knowledge of related patents PamLab's product labels, package information and marketing materials are denied as they pertain to Macoven, and as they pertain to the other defendants, are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. In all other respects, the allegations of paragraph 114 are denied.

115. For this response to the allegations of paragraph 115, defendant Macoven incorporates all of its previous responses to the allegations of paragraphs 1-114.

116. The allegations of paragraph 116 as they pertain to Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

117. The allegations of paragraph 117 are denied.

118. The allegations of paragraph 118 are denied.

119. The allegations of paragraph 119 are denied.

120. The allegations of paragraph 120 that upon information and belief, Defendants have knowledge of the '778 patent by virtue of Defendants' knowledge of related patents on PamLab's product labels, package information and marketing materials are denied as they pertain

to Macoven, and as they pertain to the other defendants, are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. In all other respects, the allegations of paragraph 120 are denied.

121. For its response to the allegations of paragraph 121, defendant Macoven incorporates all of its previous responses to the allegations of paragraphs 1-120.

122. The allegations of paragraph 122 as they pertain to Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

123. The allegations of paragraph 123 are denied.

124. The allegations of paragraph 124 are denied.

125. The allegations of paragraph 125 are denied.

126. The allegations of paragraph 126 that upon information and belief, Defendants have knowledge of the '490 patent by virtue of Defendants' knowledge of related patents on PamLab's product labels, package information and marketing materials are denied as they pertain to Macoven, and as they pertain to the other defendants, are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. In all other respects, the allegations of paragraph 126 are denied.

127. For its responses to the allegations of paragraph 127, defendant Macoven incorporates all of its previous responses to the allegations of paragraphs 1-126.

128. The allegations of paragraph 128 as they pertain to Macoven are denied, and as they pertain to the other defendants are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations.

129. The allegations of paragraph 129 are denied.

130. The allegations of paragraph 130 are denied.

131. The allegations of paragraph 131 are denied.

132. The allegations of paragraph 132 that upon information and belief, Defendants have knowledge of the '040 patent by virtue of the identification of the '040 patent on the METANX<sup>®</sup>, Neevo DHA<sup>®</sup>, Cerefolin NAC<sup>®</sup>, and DEPLIN<sup>®</sup> product labels, package information and marketing materials are denied for lack of knowledge or information sufficient to form a belief as to the truth of the allegations. In all other respects, the allegations of paragraph 132 are denied.

133. Plaintiffs' jury demand does not require an answer.

134. Defendant Macoven denies that plaintiffs are entitled to any of the relief sought in their Prayer for Relief.

135. All remaining allegations not otherwise answered above are denied.

### **AFFIRMATIVE DEFENSES**

For its affirmative defenses, defendant Macoven avers as follows:

1. Plaintiffs' Complaint fails to state a claim upon which relief may be granted.
2. Venue of the action is inconvenient in this judicial district.
3. Defendant Macoven has not infringed, and is not infringing, directly or indirectly, any valid claim of the patents-in-suit.
4. Each claim of the patents-in-suit is invalid for failure to comply with one or more requirements of Title 35, United States Code, including but not limited to, 35 USC §§ 102, 103, 112, and/or 116.
5. Plaintiffs' claims are barred on grounds of waiver, laches, and/or estoppel.
6. Plaintiffs' claims are barred on grounds of unclean hands.

7. Plaintiffs' claims are barred by reason of estoppel arising from and/or in view of remarks, representations, concessions, amendments and/or admissions made during the prosecution of the respective applications that matured into the patents-in-suit.

8. Plaintiffs' claims are barred by their failure to mitigate damages they allegedly have suffered.

9. Plaintiffs' failed to properly mark their patented articles as required by 35 U.S.C. § 287.

10. Defendant Macoven reserves the right to add defenses discovered during the course of discovery up to, and including, the time of trial.

### **COUNTERCLAIM**

For its Counterclaim, defendant/counterclaimant Macoven alleges as follows:

1. Macoven Pharmaceuticals, L.L.C. ("Macoven") is a Louisiana limited liability company having a principal place of business at 33219 Forest West Dr., Magnolia, TX 77354.

2. Upon information and belief, Merck & Cie ("Merck") is a Swiss Corporation with a principal place of business at WeissHausmatte 6460 Altdorf, Switzerland.

3. Upon information and belief, South Alabama Medical Science Foundation ("SAMSF") is a not for-profit research corporation organized and existing under the laws of the State of Alabama with a principal place of business at 307 University Blvd., P.O. Box U-1060, Mobile, Alabama.

4. Upon information and belief, PamLab, L.L.C. ("PamLab") is a Louisiana corporation with a principal place of business at 4099 Highway 190, Covington, Louisiana 70433.

5. This action arises under the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, Title 35 U.S.C. § 271, *et seq.* An actual, substantial, and continuing justiciable controversy exists between Macoven and plaintiffs with respect to which Macoven requires a declaration of its rights by this Court. At present, the controversy relates to the non-infringement and/or invalidity of the United States Patent Nos. 5,997,915, 6,011,040, 6,254,904, 6,673,381, 7,172,778, 7,674,490 (collectively the “patents-in-suit”), and plaintiffs’ right to threaten and/or maintain a suit for infringement on the patents-in-suit. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and under Rule 13 of the Federal Rules of Civil Procedure. Plaintiffs have submitted themselves to the Court’s jurisdiction and to venue in this judicial district by the filing of their Complaint against Macoven herein.

6. Plaintiffs have represented that SAMSF is the owner by assignment of United States Patent Nos. 5,997,915, 6,254,904, 6,673,381, 7,172,778, 7,674,490, that Merck is an exclusive licensee under these patents, and that Merck has granted PamLab an exclusive sublicense under these patents in the field of medical foods, foods for special dietary uses and prenatal and postnatal prescription vitamins.

7. Plaintiffs have represented that Merck is the owner by assignment of United States Patent No. 6,011,040 and that PamLab is an exclusive licensee under the patent in the field of medical foods, foods for special dietary uses and prenatal and postnatal prescription vitamins.

8. Plaintiffs have accused Macoven of infringing the patents-in-suit.

## **FIRST COUNTERCLAIM**

### **DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT**

9. Macoven repeats, realleges, and incorporates by reference each and every allegation set forth in paragraphs 1-8 of this Counterclaim as if fully set forth herein.

10. This is an action for declaratory judgment of non-infringement of any valid claim of the patents-in-suit.

11. Plaintiffs allege that Macoven infringes each of the patents-in-suit in the State of Texas and in this judicial district.

12. Macoven has not infringed, and is not infringing, either directly or indirectly, any valid claim of the patents-in-suit.

13. There is an actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, between plaintiffs and Macoven, as to whether Macoven infringes any valid claim of the patents-in-suit.

14. Macoven desires and requests a judicial determination and declaration of the respective rights and duties of the parties in regard to the disputes recited in paragraphs 9-13 above. Such a determination and declaration are necessary and appropriate at this time so the parties may ascertain their respective rights and duties regarding the non-infringement of the patents-in-suit.

## **SECOND COUNTERCLAIM**

### **DECLARATORY JUDGMENT OF PATENT INVALIDITY**

15. Macoven repeats, realleges, and incorporates by reference each and every allegation set forth in paragraphs 1-14 of this Counterclaim as if fully set forth herein.



16. This is an action for declaratory judgment of invalidity of any and all claims of the patents-in-suit.

17. The patents-in-suit, and each claim thereof, is invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including but not limited to, 35 U.S.C. §§ 102, 103, 112, and/or 116.

18. There is an actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, between plaintiffs and Macoven, as to whether there exist any valid claim of the patents-in-suit.

19. Macoven desires and requests a judicial determination and declaration of the respective rights and duties of the parties in regard to the disputes recited in paragraphs 15-18 above. Such determination and declaration is necessary and appropriate at this time so the parties may ascertain their respective rights and duties regarding the invalidity of the patents-in-suit.

#### **JURY DEMAND**

20. Defendant Macoven requests a trial by jury of all issues so triable herein.

#### **PRAYER FOR RELIEF**

WHEREFORE, Defendant/Counterclaimant Macoven Pharmaceuticals, L.L.C. prays for the following relief from the Court:

1. Judgment dismissing plaintiffs' Complaint with prejudice;
2. Judgment in favor of Macoven, sustaining its defenses;
3. Judgment declaring that Macoven has not and does not infringe, either directly or indirectly, any valid claim of the patents-in-suit;
4. Judgment declaring that the patents-in-suit, and each claim thereof, are invalid, void, and without any force or effect against Macoven, its officers, agents, servants, employees, and attorneys;

5. Judgment deeming this to be an “exceptional” case within the meaning of 35 U.S.C. § 285 entitling Macoven to an award of its attorneys’ fees, expenses, and costs incurred in this action;

6. Judgment awarding Macoven its costs associated with this lawsuit; and

7. For such other and further relief, at law or in equity, and on Macoven’s behalf, as this Court deems just and proper.

DATE: March 12, 2012

Respectfully submitted,

By: /s/ Robert L. Waddell (by permission Donald W. Washington)

Robert L. Waddell, T.A.

*pro hac vice*

Donald W. Washington

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ATTORNEYS FOR DEFENDANT,  
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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3) on March 12, 2012.

/s/ Donald W. Washington